

REMARKS/ARGUMENTS

On March 24, 2004, applicant filed a Preliminary Amendment which the Examiner apparently did not have in his file at the time of the most recent examination resulting in the Office Action dated January 7, 2005. Also enclosed is a copy of the post card identifying this application and the Preliminary Amendment containing claims 50-154 date stamped received by the U.S.PTO on March 24, 2004. A copy of the cancelled check for excess claim fees accompanying the Preliminary Amendment filed March 24, 1004 is also enclosed.

The claims 50-147 in the Preliminary Amendment correspond substantially with the originally presented claims 50-147 with the following exceptions. Independent claim 99 was amended to change line 3 as indicated on the attached copy of the Preliminary Amendment and the claims 100-147, all dependent upon claim 99, were amended to recite the phrase "in combination with the substance, said substance including at least one medicament". Thus claims 99-147 correspond substantially with originally presented claims 99-147. Claim 50 is identical to the originally presented claim 50 and is indicated allowable by the Examiner. The remaining claims 150-154 are all dependent upon claim 99 which in unamended form was indicated allowable by the Examiner.

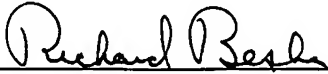
The Office Action indicates claims 50-147 are allowed and that claims 1-49 are rejected. Claims 1-49, however, were previously cancelled in the Preliminary Amendment and applicant confirms that cancellation. Because the Examiner has allowed claims 50-147 with independent claim 50 corresponding identically to claim 50 of the previously filed Preliminary Amendment and claims 99-147 corresponding substantially to claims 99-147 originally presented with but minor amendments and since the added claims 150-154 are dependent upon independent claim 99,

HENLEY et al
Appl. No. 10/807,295
January 18, 2005

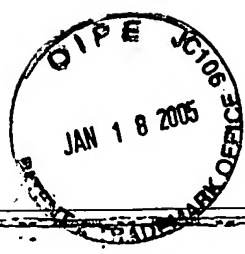
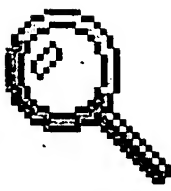
applicants submit that the application is now in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

HENLEY et al

Atty. Ref.: 3589-56; Confirmation No.

Appl. No.

Group:

Filed:

Examiner:

For: ELECTROKINETIC DELIVERY OF MEDICAMENTS

* * * * *

March 24, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRELIMINARY AMENDMENT

In order to place the above-identified application in better condition for examination, please amend the application as follows:

AMENDMENTS TO THE SPECIFICATION:

Please replace paragraph 0001 with the following paragraph.

[0001] This application is a divisional of application Serial No. 10/245,337, filed September 18, 2002, now U.S. Patent No. _____ which is a division of Serial No. 09/584,138, filed May 31, 2000, now U.S. Patent No. 6,477,410 of common assignee herewith, the entire contents of which are incorporated herein by reference.

Please replace paragraph [0009] with the following amended paragraph:

[0009] For example, by employing the device and the applicator hereof, it is possible to electrokinetically deliver medicaments such as anti-virals, for treating human papilloma virus, (HPV), e.g., warts (common, flat, plantar and genital), examples of which are Imiquimod® sold as Aldara™ by 3M for genital warts, a type (HPV), Acyclovir®, sodium salicylate, tretinoin, benzoyl peroxide, bleomycin, interferons, Podocon-25, OTC products such as Wart Off by Pfizer and Compound W by MedTech or anti-picornavirus class substances, e.g., Pleconaril, to treat coughs and colds, anti-inflammatory medicaments such as dexamethasone and anti-bacterial agents, proteins, as well as steroids and salts thereof, non-steroidal anti-inflammatory drugs (NSAIDs), and salts thereof, hormones, cytokines, viruses, bacteria, DNA, RNA, (and fragments of both), antihistamines, oligonucleotides, anti-proliferative agents (cancer), specifically 5-fluorouracil (5-FU) and cisplatin, Efudex, or a combination of 5-FU and soviudine, anti-angiogenics such as thalidomide, antibiotics, peptides and peptidomimetics and assemblages of amino acids, phenols and polyphenols, an example of which is PolyphenonE and cosmetic agents, such as retinoids, e.g.,

hyaluronic acid, vitamins and/or water, skin bulking agents, e.g., collagen, reactive monomers which may polymerize under the skin in non aqueous carriers and be activated by water, botulinum toxins, e.g. botox, bleaching agents, e.g., Eldopaque 4% by ICN Pharmaceuticals, or a combination of Ketorolac, hydroquinone 4%, Glycolic Acid, lactic acid with suitable vehicle and anesthetics, such as lidocaine, xylocaine, prontosol, prilocaine, fetanyl, remifentanyl, sufentanyl, alfentanyl, novocaine, procaine, morphine HCL and EMLA either in stand alone fashion or with a vasodilator such as epinephrine. Also, medicaments which inhibit fusion between the plasma membrane and viruses and other adventitious agents to prevent entry by viruses and/or other adventitious agents into cells may also be electrokinetically delivered, e.g., behenyl alcohols such as ~~n-docosanol~~ n-docosanol, its analogs or derivatives. Hair growth may be stimulated by Propecia (finasteride), minoxidil, blocking antidihydrotestosterones or antidihydroestrogens. Hair removal may be accomplished by dyeing the hair and or hair root to facilitate removal by laser means or by electrokinetically using, e.g., dihydrotestosterone or dihydroandrogens or dihydroestrogens. Using pigments, tattoos, either temporary (reversible) or permanent may be applied to a treatment site and tattoos when permanent may be removed using suitable medicaments and the instant invention. Water soluble dyes and decals or templates may be employed in conjunction with the device and applicators. Prostate conditions e.g., prostatitis may be treated with antineoplastics. Additionally, the diagnostic sweat test for cystic fibrosis using pilocarpine, peripheral vascular disease using vasodilators, eye (corneal) treatment using fluorescein, acne treatments with one or more steroids, NSAIDs, such as

ketorolac or medicaments such as Benzamycin, benzoyl peroxide, cleocin, T-Stat, over the counter (OTC) products two examples of which are Clearasil and Benzac or Accutane, tazarotene sold as Tazorac, adapalene sold as Differin by Allergan and Galderma respectively or azelaic acid, a topical cream also sold by Allergan, erythromycin as well as combinations of such medicaments may be electrokinetically delivered. Psoriasis may be treated with an antimetabolite, retinoids, synthetic vitamin D, i.e., calcipotriene, cyclosporin A (CSA), Aristocort, from Lederle, anthrax-derm, by Dermik, methotrexate, cortisone like compounds psoralen or anthralin. Eczema and contact or atopic dermatitis may be treated with corticosteroids or antihistamines. Spider veins may be treated with antiangiogenics, or coagulants (clotting factors or fragmented cellulose polymer). Fluoride treatment of exposed single site hypersensitive dentin may be performed with this device and applicator system. Canker sores and RAS may be treated with, e.g., benzoin or sodium fluoride. Post herpetic neuralgia may be treated with local anesthetics mentioned throughout this disclosure and/or with antivirals, e.g., Acyclovir or combinations of anesthetic and antiviral. Erectile dysfunction may also be treated (transcutaneously at site of concern) using prostaglandins such as PGE or alprostadil, nitroglycerin, and the like or papaverine, yohimbine and the like or sildenafil citrate, i.e., viagra, or apomorphine HCl. Other diagnostic uses i.e., removal or extraction of animal or human bodily material, e.g., fluids, versus delivery of medicament include as examples, allergy screening, e.g., using an electrode mounted array of antigens with a multiplexed-multi-channel application electrode, glucose monitoring and drug testing using electrode mounted

specific binders (binder assay) combined with reverse iontophoretic plasma extraction. As a further diagnostic application, body material such as fluids can be extracted into a pad on the electrokinetic device, for example, by reverse iontophoresis. Wounds such as scrapes, cuts, burns, plant allergies, punctures and insect bites or stings can be treated with antihistamines, antibiotics, anti-infectives such as bacitracin, Diprolene, topical steroids, and the like, aloe or aloe containing products or OTC products such as Ambesol, Lanocaine and the like, other wound healing agents, such as epidermoid derived growth factors as well as peptides that modulate the inflammatory response and modulators of collagen deposition and modeling as well as other wound healing agents. all electrokinetically delivered. Pre-treatment may also include desensitizing agents such as the aforementioned analgesics or salicylic acid. Pruritis, dry skin and keratosis may also be treated using, cortisones and the like, Benadryl itch crème, Lazer crème or EMLA and the like. Actinic keratoses may be treated by electrokinetic delivery of aminolevulinic acid as well as other established antimetabolite agents such as methotrexate, 3% DICLOFENAC IN 2.5% hyaluronic acid, 5FU, 5FU and isotretinoin, and the like. Bursitis or mild arthritis may be treated with magnesium sulfate or Dororac from Genderm.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-49. (Cancelled).

50. (Original) A method of treatment by electrokinetic self-administration of a medicament into a treatment site for an individual, comprising:

providing a device shaped in part to conform to at least a portion of an individual's finger and having a self-contained power source, first and second electrodes, and a substrate in electrical contact with said first electrode and having an exposed contact surface;

providing at least one of an electrokinetically transportable medicament or a medicament with an electrically conductive carrier therefor;

releasably retaining the device on the individual's finger, with the second electrode in electrical contact with the individual's finger;

providing said at least one medicament in contact with said substrate or the treatment site;

while the device remains retained on the individual's finger, placing the contact surface of said substrate into contact with the individual's treatment site and causing electrical current to flow through said first electrode, the electrically transportable medicament or the conductive carrier, the treatment site, the individual's body, said second electrode and said power source to electrokinetically drive the medicament into the treatment site.

51-98. (Cancelled).

99. (Currently amended) A delivery device for self-administration of a substance to a treatment site on an individual, comprising: a self-contained disposable applicator including a pad for ~~containing~~ applying the substance to the treatment site, a power supply, a first electrode overlying said pad and electrically connected to said power supply and a second electrode having a tactile surface in electrical contact with said power supply and lying on a side of said applicator remote from said pad, said second electrode having an electrically conductive material overlying the tactile surface, whereby, upon the individual's hand or a portion thereof in contact with said tactile surface of said second electrode holding the applicator pad against the treatment site, an electrical circuit is completed between the first electrode through the treatment site and the second electrode via the tactile surface, the electrically conductive material and the individual's hand and body for electrokinetically driving the substance into the treatment site.

100. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein delivery of the at least one medicament to the treatment site at least aids in treatment or prevention of diseases or other abnormal or cosmetic conditions of skin or mucocutaneous membrane.

101. (Currently amended) The device according to Claim 99 in combination with the substance said substance including at least one medicament, and wherein delivery

of the at least one medicament to the treatment site at least aids in treatment or prevention of infection.

102. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament ~~to the treatment site~~ is at least intended to treat or prevent bacterial infection of skin.

103. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat or prevent viral infection of skin.

104. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat or prevent microbial infection of skin.

105. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to stimulate hair growth.

106. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat a wound.

107. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat acne.

108. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat psoriasis.

109. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat eczema or contact or atopic dermatitis.

110. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat pruritis, dry skin, or keratosis.

111. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat actinic keratoses.

112. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat spider veins.

113. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein delivery of the at least one medicament is at least intended to treat skin cancer.

114. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein delivery of the at least one medicament to the treatment site at least relieves pain.

115. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat a herpetic symptom.

116. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat post-herpetic neuralgia.

117. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is an antiviral.

118. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is an anesthetic.

119. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat an inflammatory condition.

120. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is dexamethasone.

121. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one anesthetic selected from the group

consisting of lidocaine, xylocaine, prilocaine, prilocaine, fetanyl, remifentanyl, sufentanyl, alfentanyl, novocaine, procaine, morphine HCl and EMLA.

122. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament. and wherein said at least one medicament comprises an anti-proliferative agent or an anti-angiogenic agent.

123. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament. and wherein said at least one medicament comprises at least one chemical selected from the group consisting of 5-fluorouracil, cisplatin, Efudex, soviudine and thalidomide.

124. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament. and wherein said at least one medicament is at least intended to treat a varicella zoster symptom.

125. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament. and wherein said at least one medicament comprises acyclovir.

126. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament. and wherein said at least one medicament comprises a chemical selected from the group consisting of analogs and derivatives of acyclovir.

127. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament. and wherein said at least one medicament comprises at least penciclovir or famciclovir.

128. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises a behenyl alcohol.

129. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises n-docosanol.

130. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical selected from the group consisting of analogs and derivatives of n-docosanol.

131. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises 5-iodo-2 deoxyuridine (IUDR).

132. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical selected from the group consisting of cytosine arabinoside (Ara-C), adenine arabinoside (Ara-A), adenine arabinoside monophosphate (Ara-AMP), arabinofuranosyl hypoxanthine (Ara-Hx), phosphonoacetic acid (PAA), thymine arabinoside (Ara-T), 5'-amino-2', 5'-dideoxy-5-iodouridine (AIU), 1-beta-D-arabinofuranosyl-E-5-(2-bromovinyl)uracil (BV-ara-U), 1-beta-D-arabinofuranosyl-E-5(2-chlorovinyl)uracil (CV-ara-U), halogenated deoxytidines BrCdR and ICdR, and bromovinyldeoxyuridine (BVDU).

133. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises an antiviral and an anesthetic.

134. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament is at least intended to treat an infection by a human papilloma virus.

135. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical selected from the group consisting of Imiquimod, sodium salicylate, tretinoin, benzoyl peroxide, bleomycin, interferons, Podocon-25, Wart Off and Compound W.

136. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises an antibiotic.

137. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical selected from the group consisting of finasteride, minoxidil, antidihydrotestosterones and antidihydroestrogens.

138. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at

least one medicament comprises at least a steroidal or non-steroidal anti-inflammatory drug (NSAID).

139. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical or biologic selected from the group consisting of benzamycin, benzoyl peroxide, cleocin, T-Stat, Clearasil, Benzac, Accutane, tazarotene, adapalene, azelaic acid and erythromycin.

140. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical or biologic selected from the group consisting of anesthetics, analgesics, and other desensitizing agents.

141. (Cancelled).

142. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical or biologic selected from the group consisting of vasodilators, antihistamines, antimetabolites, immunosuppressives, and antineoplastic agents.

143. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said at least one medicament comprises at least one chemical or biologic selected from the group consisting of antiandrogens, beta blockers, beta-adrenergic antagonists, catecholamines, modulators of collagen deposition, and sympathomimetics.

144. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein said first electrode includes a multi-channel electrode, each electrode channel being electrically driven in a current isolated fashion through a corresponding plurality of individual current loops with each channel receiving substantially the same current level.

145. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and including a current driver, said first electrode including a plurality of current distributive channels and a plurality of current limiters coupled between said driver and said channels to provide substantially the same current level in each said channel.

146. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and wherein the device is disposable after one-time usage.

147. (Currently amended) The device according to Claim 99 in combination with the substance, said substance including at least one medicament, and including a vibratory element carried by said device and electrically coupled to said power source for inducing ultrasonic vibration into the treatment site.

148. (Cancelled).

149. (Cancelled).

150. (New) The device according to claim 99 in combination with the substance, said substance being contained within said pad.

151. (New) The device according to claim 99 in combination with the substance, said substance being applied to said pad on a side thereof opposite said first electrode.

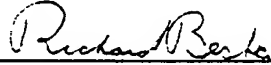
152. (New) The device according to claim 99 wherein said second electrode overlies said first electrode on a side of the applicator remote from said pad.

153. (New) The device according to claim 99 in combination with the substance, said substance comprising an anti-fungal.

154. (New) The device according to claim 99 in combination with the substance, said substance at least aiding in the treatment or prevention of a disease condition caused by suspected to be caused by a fungus.

Respectfully submitted,

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